# Perspectives on Post-Printing Considerations

Matthew Di Prima, PhD
US Food and Drug Administration
CDRH/OSEL/DAM

Public Workshop – Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing. October 8th 2014

# Workshop Goals on Topic

- Not all devices or additive manufacturing technologies have the same risks or degrees of concern
- What needs to be considered during the design process and what needs to be communicated to the FDA
- How have these concerns been addressed already?
- Are there concerns/challenges not mentioned

# Post-Printing Considerations

- Post-Printing Considerations are concerns related to device performance that are relevant after the printing process is complete and include but not limited to:
  - Mechanical Properties
  - Physical Properties
  - Cleanliness of the finished part
  - Sterility and Pyrogenicity

# Mechanical Properties

- Adhesion between print layers may lead to anisotropy in mechanical properties
  - Polymer systems can have as little as 15% of the tensile strength in the build direction (Ahn et al 2002)
  - A number of fatigue studies have been performed to investigate effect of build direction on fatigue strength
  - A number of medical devices, like spinal cages, will experience complex in-vivo loading conditions that may exacerbate delamination/fatigue failures in additively manufactured parts
  - Patient matched devices may lead to great challenges in determining best print orientation for mechanical performance

# Mechanical Properties cont.

- Additive manufacturing may limit the control over the final material microstructure and therefore impact mechanical properties
  - Additives are needed for a number of SLA based systems, could impede polymer network structure
  - Control over grain size and melt consolidation difficult in metal printers

# Physical Properties

- Microporosity from printing process may serve as fatigue crack initiation sites
- Incomplete consolidation from pathing/material issues may reduce mechanical strength
- Engineered surface features may affect functional and mechanical performance

# Cleanliness

- Additive manufacturing has excess material to remove
  - Powder from powder bed systems
  - Monomer/uncured material in stereolithography systems
  - Sacrificial support structures
- Integral porous coatings
  - May serve to track excess printing materials
  - May become contaminated by debris/lubricants under final machining

# Sterility and Pyrogenicity

- Additive manufacturing allows for structural porosity and complex internal structures
  - Complex internal structures may reduce effectiveness of some sterilization techniques
  - How to validate sterility of internal surfaces and porous to non-porous interfaces
  - Endotoxin/bioburden risks with these design features

# Subject Matter Experts

- Greg Morris, GE Aviation
  - GE Aviation – Additive Road to Production
- Bill Brodbeck, PhD., STERIS Corporation
  - Perspectives on Post-Printing Considerations: Sterilization
- Tom Boland, PhD., University of Texas at El Paso
  - Cell Printing: Post-Printing Considerations

# Continuing the Discussion

- Biological Considerations of Final Device Break Out Session
  - Room 2, 14:53 – 15:53
- Physical and Mechanical Assessment of Final Device Break Out Session
  - Room 2, 16:00 – 17:00
- Docket open for comments and responses

  http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0432-0001